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4 510(k) Summary

510(k) Summary of Safety and Effectiveness

Date:
February 22, 2000

Submitter:
Marquette Hellige GmbH
Munzinger Strasse 3
D-79111 Freiburg, Germany

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Device: Trade Name:
Defibrillator Responder® 3000

Common/Usual Name:
Defibrillator

Classification Names:

21 CFR 870.5300 DC-Defibrillator, Low-Energy, (including paddles)	74 LDD
21 CFR 870.5300 Defibrillators, Automatic, External	74 MKJ

Predicate Devices:

K962547	Defibrillator CardioServ P
K962551	Defibrillator CardioServ S
K973403	Electrocardiograph CardioSmart ST
K926172	Defibrillator Series 1500 Responder®
K964305	Nihon Kohden OLG-1100A PocketCap Pocket CO2 Monitor

Device Description:

The Responder® 3000 is a lightweight, portable defibrillator with ECG monitor and integrated recorder. It is equipped with an integrated pacemaker for external pacing (option).

The Responder® 3000 is offered in different versions:

one for manual defibrillation intended for adult and pediatric patient populations and
one for semiautomatic defibrillation, intended for adult patient populations, which can be switched to manual operation.

Both are capable of delivering synchronized and non-synchronized shocks.

The defibrillator can be expanded with the following options:

- the Marquette 12SL program for ECG measurement and interpretation
- the etCO_2 measuring system for analysis of the end tidal CO_2 level.
- The SpO_2 measurement.

The following electrode types can be used with the defibrillator:
Hard paddles (with integrated contact surfaces for children), adhesive pads, and internal spoons.

The defibrillator has memories for storage and documentation of the relevant procedure data:

- an event memory,
- an ECG memory,
- a trend memory and
- a memory for the 12SL analysis ECG.

The integrated 3-channel recorder can be started manually and automatically.
The defibrillator is powered from

- an optional AC power adapter which is permanently attached to the defibrillator or
- 1 or 2 plug-in batteries
- the wall mounting unit
- the vehicle mounting unit.

Batteries are recharged from one of the following sources:

- the optional AC power adapter,
- the optional wall mounting unit,
- the optional ASU 3000 battery station, or
- the optional vehicle mountung unit.

Intended Use: The Marquette Responder® 3000 is intended to be used for the emergency resuscitation of cardiac arrest victims and clinical cardiac

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dysrhythmia.
It is geared to both hospital and prehospital use. In conjunction with the vehicle mounting unit, it can also be used in an ambulance.

The Marquette Responder® 3000 is designed for external and internal defibrillation and is equipped with an integrated pacemaker for external pacing.

There are two basic models of the Marquette Responder® 3000:

- one for manual defibrillation ,
- one for semiautomatic defibrillation which can be switched to manual operation.

Both are capable of delivering synchronized and non-synchronized shocks.

In the semiautomatic mode, an analysis algorithm scans the patient's ECG to check whether or not a shockable rhythm exists.
When a shockable arrhythmia is found, the unit recommends defibrillation and automatically starts charging. In this mode, it is not possible to operate the defibrillator manually.

Additionally the Marquette Responder® 3000 is capable of monitoring the heart rate

- ECG measurement and interpretation (option)
- etCO2 measurement for analysis of the end tidal CO2 level (option)
- SpO_2 measurement to determine the percentage of functional hemoglobin saturated with oxygen in the patent's blood (option)

Technology:

The Responder® 3000 employs the same functional technology as the predicate devices.

Test Summary:

The Responder® 3000 complies with the voluntary and mandatory standards. The following quality assurance measures were applied to the development of the Responder® 3000:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Data bench testing
- Final validation

Conclusion:

The results of these measurements demonstrated that the Responder® 3000 is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Kristin Pabst
GE Marquette Medical Systems, Inc.
8200 W. Tower Avenue
Milwaukee, WI 53223

Re: K000638
Responder 3000
Regulatory Class: III (three)
Product Code: 74 MKJ, LOS, LDD, DQA, CCK
Dated: September 29, 2000
Received: October 2, 2000

Dear Ms. Pabst:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Statement of Indications for Use

Applicant: _____ Marquette Hellige GmbH, Munzinger Strasse 3, D-79111 Freiburg, Germany

510(k) Number (if known): _ unknown K000638

Device Name: _____ Marquette Responder® 3000

The Marquette Responder® 3000 is a multifunctional multiparameter defibrillator/monitor to be used by trained operators for the emergency resuscitation of cardiac arrest victims and clinical cardiac dysrhythmia.

The Responder 3000 is designed for internal and external defibrillation (including cardioversion), monitoring patient ECG and monitoring heart rate. Optional features include external transcutaneous cardiac pacing, $etCO_2$ measurement, SpO_2 measurement, and ECG measurement and interpretation (12SL). It is available in manual and semiautomatic defibrillation models. The Responder 3000 is designed for both hospital and prehospital use as well as inter- and intra-hospital transfer.

Use of the Responder 3000 monitoring and manual defibrillation functions are intended for patient populations including adult and pediatric.

Responder 3000 semiautomatic defibrillation and pacing functions are intended for adult patient populations.

Responder 3000 $etC0_2$ is intended for adult and pediatric patients older than 3 years to measure the concentration of carbon dioxide during expiration to aid in determining the patient's ventilatory status.

Responder 3000 SPO_2 is intended for adult and pediatric patients to monitor the saturation of O_2 in the patient's blood.

Responder 3000 ECG measurement and interpretation analysis program (12SL) is intended for adult and pediatric patient populations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Division of Cardiovascular & Respiratory Devices
510(k) Number K000638

Prescription Use ✓
per 21 CFR 801.109